Docket No.: OSTEONICS 3.0-454
(PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:
Pichon et al.

Application No.: 10/795,946 Group Art Unit: 3738

Filed: March 8, 2004 Examiner: Not Yet Assigned

For: FEMORAL PROSTHESIS

CLAIM FOR PRIORITY AND SUBMISSION OF DOCUMENTS

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

Applicant hereby claims priority under 35 U.S.C. 119 based on the following prior foreign application filed in the following foreign country on the date indicated:

Country	Application No.	Date
Great Britain	0305449.1	March 10, 2003

In support of this claim, a certified copy of the original foreign application is filed herewith.

Dated: June 9, 2004

Respectfully submitted,

By _____
Raymond W. Augustin
Registration No.: 28,588
LERNER, DAVID, LITTENBERG,
KRUMHOLZ & MENTLIK, LLP
600 South Avenue West
Westfield, New Jersey 07090
(908) 654-5000
Attorney for Applicant

I hereby certify that this correspondence is being deposited with the U.S. Postal Service with sufficient postage as First Class Mail, in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on the date shown below.

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(Raymond W. Augustin)

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The Patent Office
Concept House
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NP10 8QQ

I, the undersigned, being an officer duly authorised in accordance with Section 74(1) and (4) of the Deregulation & Contracting Out Act 1994, to sign and issue certificates on behalf of the Comptroller-General, hereby certify that annexed hereto is a true copy of the documents as originally filed in connection with the patent application identified therein.

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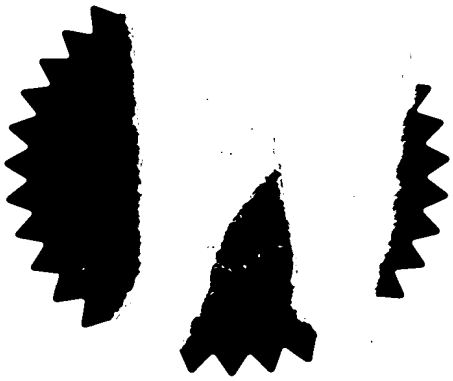

Signed J Evans.

Dated 15 March 2004

Patents Form 1/77

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Request for grant of a patent

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10 MAR 2003

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1. Your reference

AJBB/SPY/H.116

11MAR03 E791060-1 002624
P01/7700 0.00-0305449.1

2. Patent application number
(The Patent Office will fill in this part)

0305449.1

3. Full name, address and postcode of the or of each applicant *(underline all surnames)*

BENOIST GIRARD SAS

203, Boulevard de la Grande Delle - B.P.8.
14201 Hérouville-Saint-Clair Cédex
FRANCE

Patents ADP number *(if you know it)*

If the applicant is a corporate body, give the country/state of its incorporation

FRANCE 8098337001

4. Title of the invention

FEMORAL PROSTHESIS

5. Name of your agent *(if you have one)*

G.F. REDFERN & CO.

"Address for service" in the United Kingdom to which all correspondence should be sent *(including the postcode)*

7 Staple Inn,
Holborn,
London,
WC1V 7QF

Patents ADP number *(if you know it)*

1412002 14 MAR 2003

6. If you are declaring priority from one or more earlier patent applications, give the country and the date of filing of the or of each of these earlier applications and *(if you know it)* the or each application number

Country	Priority application number *(if you know it)*	Date of filing *(day / month / year)*

7. If this application is divided or otherwise derived from an earlier UK application, give the number and the filing date of the earlier application

Number of earlier application	Date of filing *(day / month / year)*

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a) any applicant named in part 3 is not an inventor, or
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Description	12
Claim *(s)*	
Abstract	1
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Statement of inventorship and right to grant of a patent *(Patents Form 7/77)*	
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Any other documents *(please specify)*	

11. I/We request the grant of a patent on the basis of this application.

Signature

Date
10 March 2003

12. Name and daytime telephone number of person to contact in the United Kingdom

A.J. Bridge-Butler
020 7242 7680

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FEMORAL PROSTHESIS

This invention relates to a femoral prosthesis which is for insertion into the bone canal of a femur and is particularly, although not exclusively, applicable for use in revision surgery.

When carrying out revision surgery it is usually necessary to provide rigid support of the proximal end of the bone canal due to this end of the canal tending to be opened out when the previous prosthesis was removed. It is known to provide a filling in this area and it is also known to provide a proximal sleeve on the prosthesis to accommodate the lack of bone.

With known sleeves it is difficult for the surgeon to judge the required tapering thickness of such a sleeve so that maximum support is obtained and, in any case, it is usually necessary for the sleeve to be attached to the stem of the prosthesis prior to assembly.

The present invention is intended to overcome some of the difficulties referred to above by providing a sleeve which can be fitted to a prosthesis before or after the stem of the prosthesis has been placed in position in the bone canal.

According to the present invention a femoral prosthesis includes a stem for insertion in a femoral canal and a shoulder and neck portion characterised by a proximal sleeve having an outer circumferential wall and comprising two or more proximal sleeve components, each of which provides part of the circumferential outer surface of the sleeve, and means for securing the proximal sleeve components in position at the proximal end of the stem.

Thus, it is now possible for the surgeon to fix the stem in position in the bone canal and then add the two or more proximal sleeve components enabling him to use

sleeve components which adequately fit the bone canal walls to provide a proximal sleeve of correct shape.

In one preferred construction two proximal sleeve components are provided and which are located respectively on the medial and lateral sides of the stem.

In an alternative construction two proximal sleeve components can be provided and which are located respectively on the posterior and anterior sides of the stem.

In another alternative construction three or more proximal sleeve components are provided which are arranged around the stem.

With all these arrangements each proximal sleeve component can be accompanied by two or more sleeve components which are of the same interior shape but which have alternatively shaped part-circumferential outer surfaces. This provides a modular construction in which the final shape of the proximal sleeve can be varied to suit the patient.

Preferably the shoulder and neck portion of the stem are separately attachable to the stem before or after the stem has been inserted into the canal bone.

The operating surgeon now therefore has a modular construction in which the appropriate sleeve portions and the neck can be fitted to the stem after it has been inserted into the canal bone.

Preferably the neck portion will provide means to attach a ball head or the ball head can be integral with the neck portion.

The various proximal sleeve components can be secured to the proximal end of the stem by any convenient attachment means, for example, they could be arranged to be held in place by screws which locate on the stem or locate on another proximal head portion to allow them to be pulled together into tight engagement or they could even be arranged to clip onto the stem. The detachable neck can be located on a taper on the upper part of the stem and held in position by a screw or clip.

The prosthesis can also include a support for the great trochanter which can be provided on one of more of the proximal sleeve portions and in a convenient arrangement the support is separately attachable to one of the proximal sleeve portions.

The surgeon may desire to fasten the various parts together before inserting the prosthesis into the bone canal and to enable him to select the correct shapes for the proximal sleeve components the invention can include a femoral prosthesis as set forth above in combination with a ghost or trial prosthesis which also comprises a stem for insertion into a femoral canal and a shoulder and neck portion and having a proximal sleeve having an outer circumferential wall and comprising two or more proximal sleeve components each of which provides part of the circumferential outer surface of the sleeve and means for securing the proximal sleeve components in position at the proximal end of the stem, the proximal sleeve components being of the same dimensions and shapes as those provided with the femoral prosthesis.

Thus equipped the surgeon can make up a ghost or trial prosthesis applying different shapes of sleeve components until he achieves what he regards as an ideal fit. Sleeve components of the same dimensions and shapes of those which he has selected for the ghost or trial prosthesis can now be applied to the femoral prosthesis itself before it is inserted into the bone.

As set forth above the neck portion can also be separately attachable to the same stem portion and the ghost prosthesis will therefore include a similar attachable stem portion thus allowing a femoral prosthesis to be constructed which is identical with the ghost prosthesis.

In an alternative arrangement, and according to a further aspect of the invention, a femoral prosthesis as set forth above can be provided in combination with a ghost or trial prosthesis comprising a stem portion with a neck portion which is adapted to receive the proximal sleeve components of the femoral prosthesis.

As before, a separate and attachable neck portion can be provided on the ghost or trial prosthesis.

With this arrangement only one set of modular proximal sleeve component is required. They are first used on the ghost prosthesis stem so that the surgeon can determine the precise shapes and proportions required and can then be transferred to the femoral prosthesis stem and neck thus again ensuring a precise fit.

The invention can be performed in various ways and some embodiments will now be described by way of example and with reference to the accompanying drawings in which :

Figure 1 is an exploded diagrammatic view of a prosthesis according to the present invention; and,

Figure 2 is a pictorial isometric view of the femoral prostheses assembled from the parts shown in Figure 1.

Figure 3 is an isometric view of a greater trochanter support;

Figure 4 is a similar view to that shown in Figure 2 but with the greater trochanter support shown in Figure 3 in position;

Figure 5 shows another construction in which the proximal sleeve components are located respectively on the posterior and anterior sides of the stem;

Figure 6 shows another alternative construction in which three or four proximal sleeve components are employed;

Figure 7 is an isometric view from above of another alternative construction;

Figure 8 is a side view of one of the proximal sleeve components;

Figure 9 is an isometric view of another proximal sleeve component;

Figure 10 is a plan view of the proximal sleeve components secured together;

Figure 11 is an isometric view of another alternative construction;

Figure 12 is a side view of another alternative construction in place in a femur; and,

Figure 13 is an exploded view of another alternative construction.

As shown in Figures 1 and 2 of the drawings a femoral prosthesis according to the present invention comprises a stem 1 having a shoulder and/or neck portion 2. The proximal end of the stem 1 has a tapered spigot 3 and the neck portion 2 has a raised boss 4 which provides a shoulder. Located within the boss 4 is a tapered

socket 5 which is shaped and dimensioned to locate on the tapered spigot 3 of the stem 1. A screw (not shown in Figure 1) is provided which can extend through a flanged opening 7 in the boss 4 and into a screw threaded opening 8 in the spigot 3 to hold the shoulder and neck portion 2 rigidly in position on the stem 1. This stem 1 can be of any convenient and well known shape for use in a bone canal.

Included in the construction is a medial proximal sleeve component 10 which has a groove 11 which is shaped to co-operate with the medial side 12 of the stem 1 and neck portion 2. The sleeve component 10 also has a trough 13 to adapt it to the distal side of the stem portion 2.

A proximal sleeve component 15 is also provided which has a groove 14 adapted to locate on the lateral side 16 of the shoulder and neck portion 2 and the stem 1.

Screw openings 17 and 18 are provided in the lateral proximal sleeve component 15 for the passage of grub screws 19 which can locate in appropriate screw threaded openings 20 and 21 in the medial component 10 to firmly attach the proximal sleeve components in position when assembled.

The free end 22 of the neck portion 2 has a taper 23 to accommodate a ball head (not shown) of known type.

Figure 2 shows the various parts assembled together in position in a femur which is indicated in broken lines 24. The medial and lateral sleeve components 10 and 15 have been fastened in position so that the upper part of the bone canal is completely filled.

As will be seen the proximal sleeve has an outer circumferential wall and comprises two proximal sleeve components each of which provides part of the circumferential outer surface of the sleeve.

In order to provide a modular construction two or more medial proximal sleeve components 10 of different dimensions and shapes are provided for alternative co-operation with the medial side 12 of the stem and similarly two or more lateral proximal sleeve components 15 of different dimensions and shapes for alternative co-operation with the lateral side of the stem and/or neck portion are provided. Thus the surgeon could have a large array of sleeve components in order to allow different combinations to be used together to provide a perfect fit.

A femoral prosthesis according to the invention can be supplied to surgeons in combination with a ghost or trial prosthesis. This ghost or trial prosthesis is identical with the femoral prosthesis and will be supplied with an array of identically shaped proximal sleeve components. Thus, the surgeon can assemble the ghost prosthesis and use it as a trial. This enables him to alter the sleeve components until he achieves the fit which he desires. The femoral prosthesis can then be made up using the appropriate parts, the ghost prosthesis removed and replaced by the femoral prosthesis itself.

In an alternative assembly the ghost or trial prosthesis need consist only of the stem and shoulder/neck. The surgeon can use this stem to assemble the prosthesis sleeve components onto the ghost or trial stem until he achieves the result he requires, the ghost or trial prosthesis together with the selected sleeve portions can be removed from the bone canal and the sleeve components transferred to the stem and neck portion of the femoral prosthesis where they can be held in place as set forth above.

The invention enables the surgeon to fit a femoral prosthesis, especially after revision surgery, which provides a more effective co-operation with the bone than other known constructions.

Figure 3 shows a support for the greater trochanter and which is in the form of an upstanding curved horn 30. The lower surface 31 is flat so that it can be placed

in position on the lateral proximal sleeve component 15. Bolt holes 32 are provided which enable the horn 30 to be bolted down into position as shown in Figure 4 by grub screws 33.

As will be seen from Figure 4 the horn 30 projects upwardly from the sleeve component 15 to provide a support for the greater trochanter. Wire loop holes 34 are provided to allow the passage of a suitable filament or filaments which can be looped around the greater trochanter.

In the construction shown in Figures 3 and 4 the greater trochanter support is attachable to the component 15 which thus enables it to be used in a modular way with the other components. However, if desired, it could be permanently and rigidly secured to the appropriate lateral proximal component.

In the construction shown in Figures 1 to 4 the proximal sleeve components are provided on the lateral and medial sides of the stem 1 but Figure 5 shows a construction in which there are two proximal sleeve components which are shaped and adapted to fit the posterior and anterior sides of the stem 1. In Figure 5 the same reference numerals are used to indicate similar parts to those shown in Figures 1 to 4. Reference numeral 40 indicates an anterior proximal sleeve component and reference numeral 41 indicates a posterior proximal sleeve component. The components are held together by grub screws 42 which act to pull the two components together and clamp them in position on the stem 1. With this arrangement the grooves 11 and 14 and trough 13 are shown in the construction of Figure 1 are split so that part of each groove and part of the trough 13 are provided on each of the proximal sleeve components 40 and 41.

The construction acts in a similar way to that shown in Figures 1 and 2 and a number of proximal sleeve components 40 and 41 are provided so that the surgeon can form a proximal sleeve which fits the upper part of the bone canal.

A support for the great trochanter, similar to that shown in Figure 3, can also be included and which will straddle the components 40 and 41. The construction of the stem 1, shoulder 4 and neck 2 are similar to that shown in Figure 1.

Figure 6 shows another alternative construction but in this arrangement three proximal sleeve components are employed. The general construction of the stem 1, shoulder 4 and neck 2 are similar to that shown in Figures 1 and 2 but the lateral proximal sleeve component 15 is replaced by an anterior proximal sleeve component 50 and a posterior sleeve component 51. The medial sleeve component 53 is similar to sleeve component 10 in Figures 1 and 2 but the circumferential length of its groove 11 is slightly less.

In this construction the circumferential length of the grooves on the inner surface of the sleeve components 50 and 51 is also somewhat less than the grooves in the components 40 and 41 shown in Figure 5 because the remainder of the contacting surface is provided by the medial sleeve component 53.

Sleeve components 50 and 51 are secured to the medial sleeve component 53 by grub screws 54 which pass through openings in the sleeve components and extend into the medial sleeve component 53.

With this construction therefore three proximal sleeve components are provided. A number of each of the sleeve components 50, 51, 53 are provided of different shapes and dimensions so that greater versatility in the shape of the proximal sleeve is achieved.

As mentioned above, in the construction shown in Figure 6 three proximal sleeve components are used but it will be appreciated that the medial proximal sleeve component 53 could also be divided into two so that there would be four components. The two medial sleeve components could be connected together by a further grub screw indicated by chain lines 55. The construction shown in Figure 6

with three components and also with four components enables the surgeon to compensate for irregularities between the sides of the bone canal.

Figures 7, 8, 9 and 10 show another construction according to the invention. In the drawings the same reference numerals are used to indicate similar parts to those shown in Figures 1 and 2 but in this arrangement the neck and stem are in one piece. This construction is most clearly shown in Figure 8. If desired such a one piece construction could also be used in the arrangements shown in Figures 1 to 6.

In the construction shown in Figure 8 however the proximal end of the stem 1 is provided with a taper 60. This taper would however be unnecessary in the construction shown in Figures 1 to 6. The two proximal sleeve components are provided by a lateral proximal sleeve component 61 which also projects to the medial side, is appropriately tapered and has a bore 62. The proximal end of the bore has a taper 63 which is adapted to engage and lock onto the taper 60 on the stem 1. Thus, the component 61 is fitted by sliding it over the stem and attaching it by the tapers 60 and 63 by simple impaction. A trough 64 is provided to accommodate the distal portion of the neck 2.

In this construction a medial proximal sleeve component 65 is in the shape of a clamp having an inner groove 66 and a shaped outer surface 67. This clamp wraps around the medial side of the lateral sleeve component 61 and is held in position by either a single grub screw 68 which passes through an opening 69 and into the lateral proximal sleeve component 61 or, as shown in Figure 10, by two grub screws 68. As will be seen from the drawings two proximal sleeve components are again provided and again the surgeon can place appropriately shaped components in position to match the bone canal.

As with the other constructions a number of alternative sleeve components can be provided so that they can be placed in position to achieve the desired filling of the bone canal.

In the construction shown in Figures 7 to 10 the taper 60 on the stem and the co-operating taper 63 on the sleeve component are arranged so that the component is placed over the stem and fixed into position but, alternatively, the direction of the tapers can be reversed and the trough 64 could be provided as a slot extending right through the sleeve component 61 so that the sleeve component could be fitted onto the stem from the reverse direction, that is over the neck 2 thus enabling the sleeve components to be placed in position with the stem in the bone canal.

Figure 11 shows another construction according to the invention which employs a medial proximal sleeve component 70 which has a bore 71 with a proximal tapered portion similar to that provided in the lateral sleeve component 61 shown in Figures 7 to 10. The sleeve also has a taper similar to the taper 60 shown in Figure 8 so that the medial sleeve component 70 is again located in position by mating tapers. A trough 73 accommodates the neck 2.

A lateral proximal sleeve component 74 engages around the lateral portion of the component 70 and is held in place by grub screws 75.

This construction again enables the surgeon to provide a suitable shape to fill the proximal end of the bone canal and a number of medial and lateral proximal sleeve components 70 and 74 can be provided so as to create a modular construction of varying shapes.

In certain femoral prostheses a collar is provided at the proximal end of the stem which can act as a "landmark" to seat the stem in the right position and which also prevents subsidence of the stem into the canal after fitting. The present invention also has provision to prevent such subsidence and to act as a "landmark" and this is provided by an abutment 80 as shown in Figure 12 in which the same reference numerals are used to describe similar parts as in Figure 1.

The abutment 80 can be formed integral with the sleeve component 10 or, and alternatively, it can be provided as a separate abutment component 81 as shown in Figure 13. The separate component 81 can be held in place by a screw or screws 82.

The components 10 which are provided with the abutment 80 can again be provided in different sizes so that the abutment is appropriate to the bone with which it is to be used. Similarly, with the construction shown in Figure 13 the abutment components 81 can also be provided in different sizes so that they can be applied by the surgeon as required.

The outer surfaces of the different parts of the apparatus can be coated or non-coated or have a specific surface texture. The surgeon can therefore choose not only the best fitting but also the best coating for each particular part.

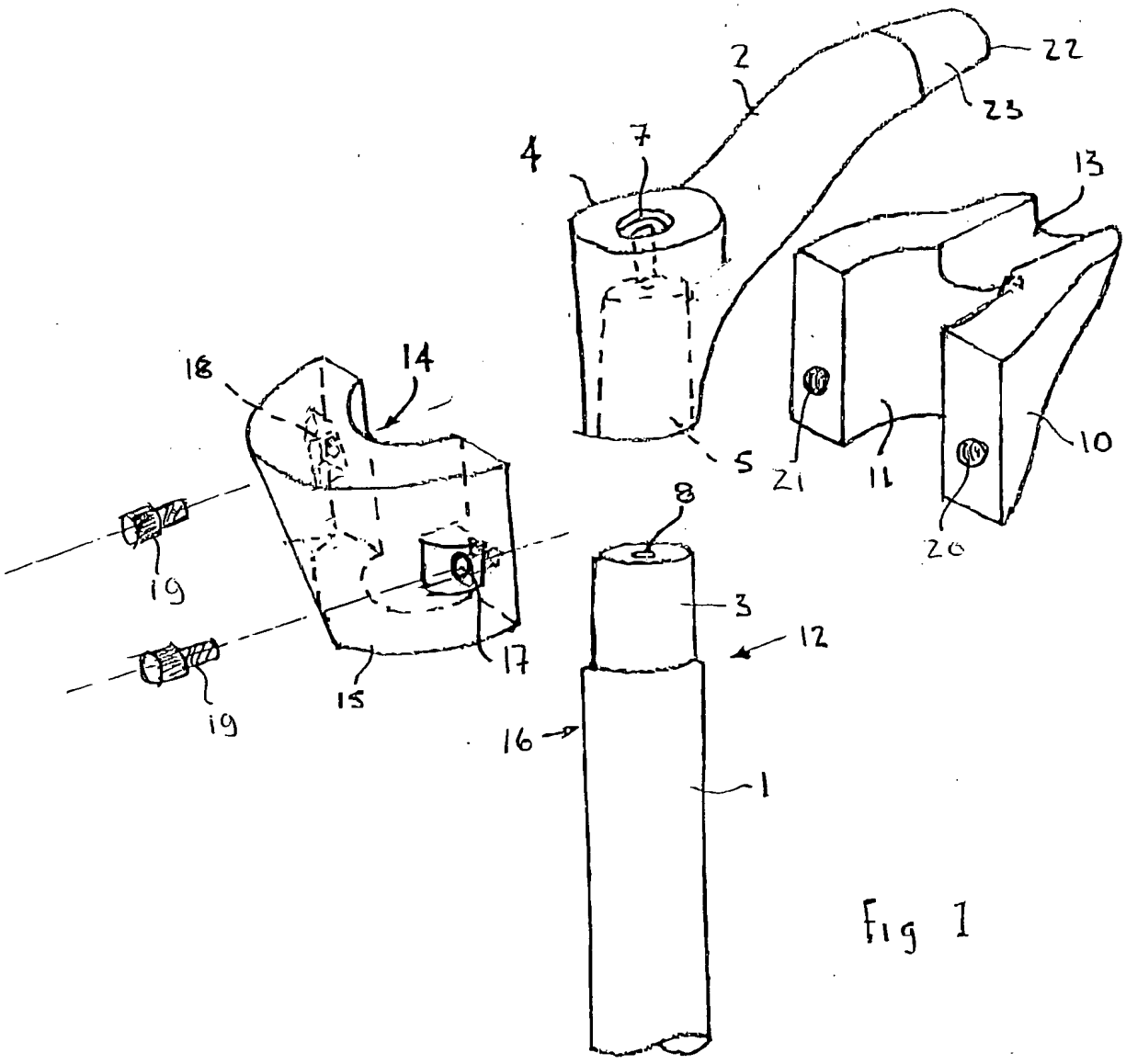

Fig 1

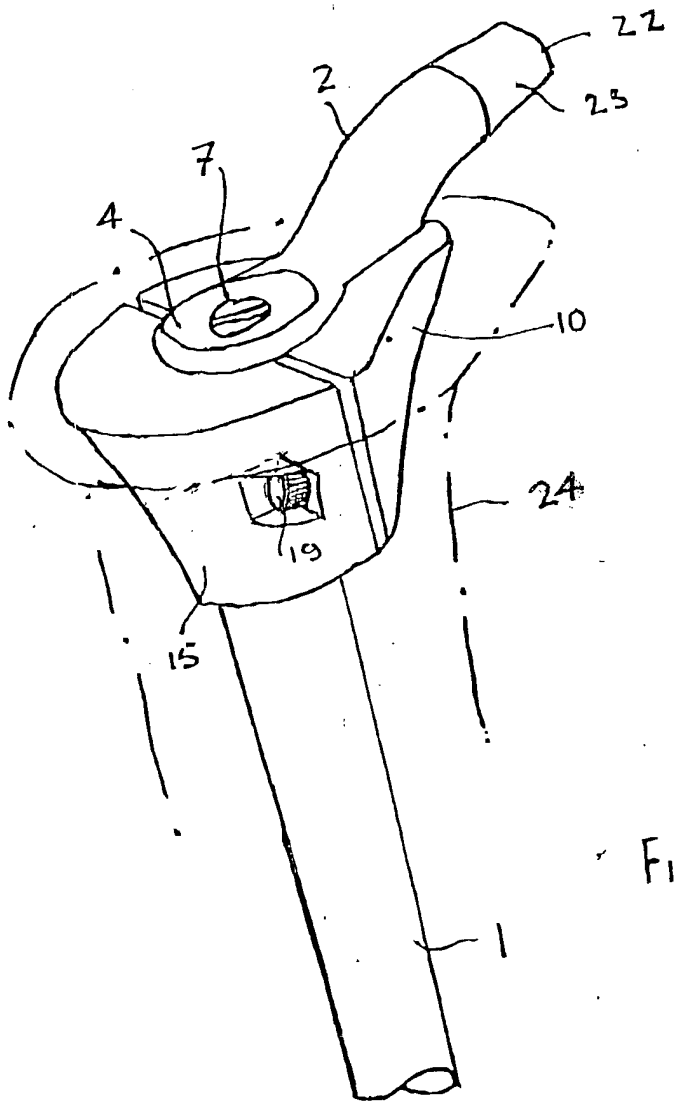

Fig 2

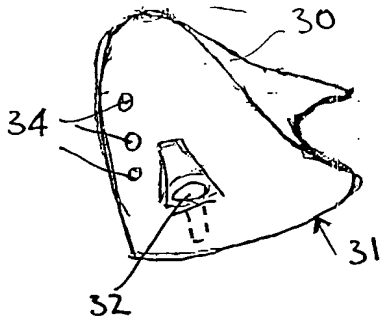

Fig 3

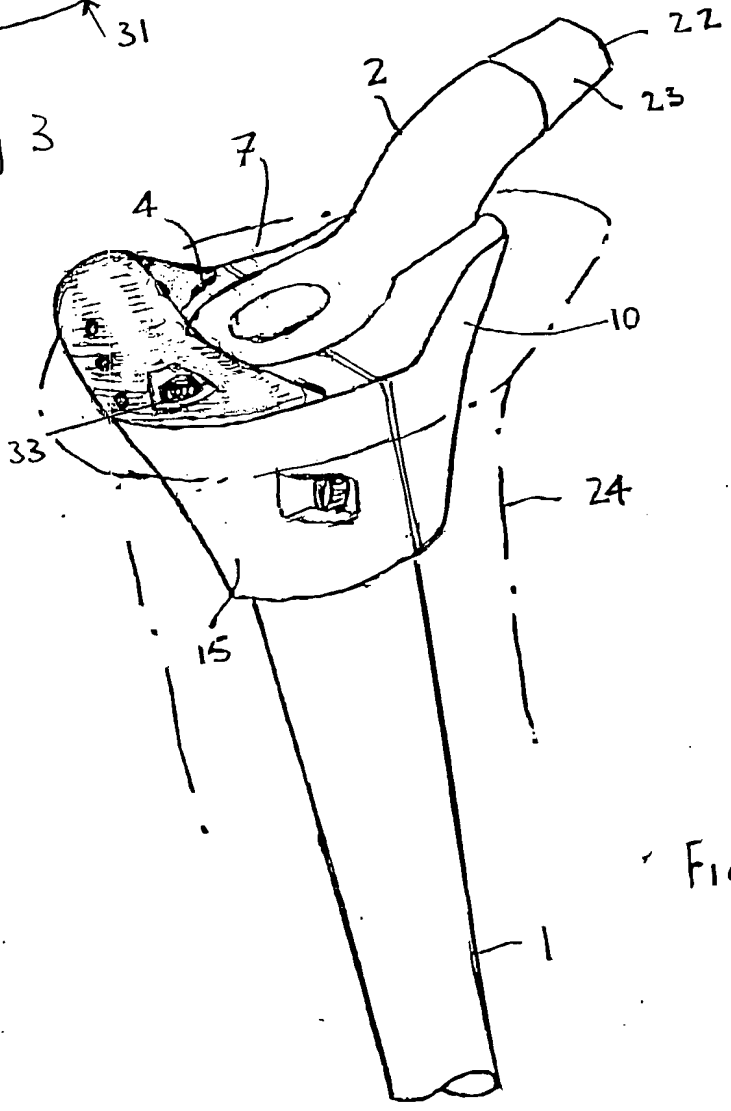

Fig 4

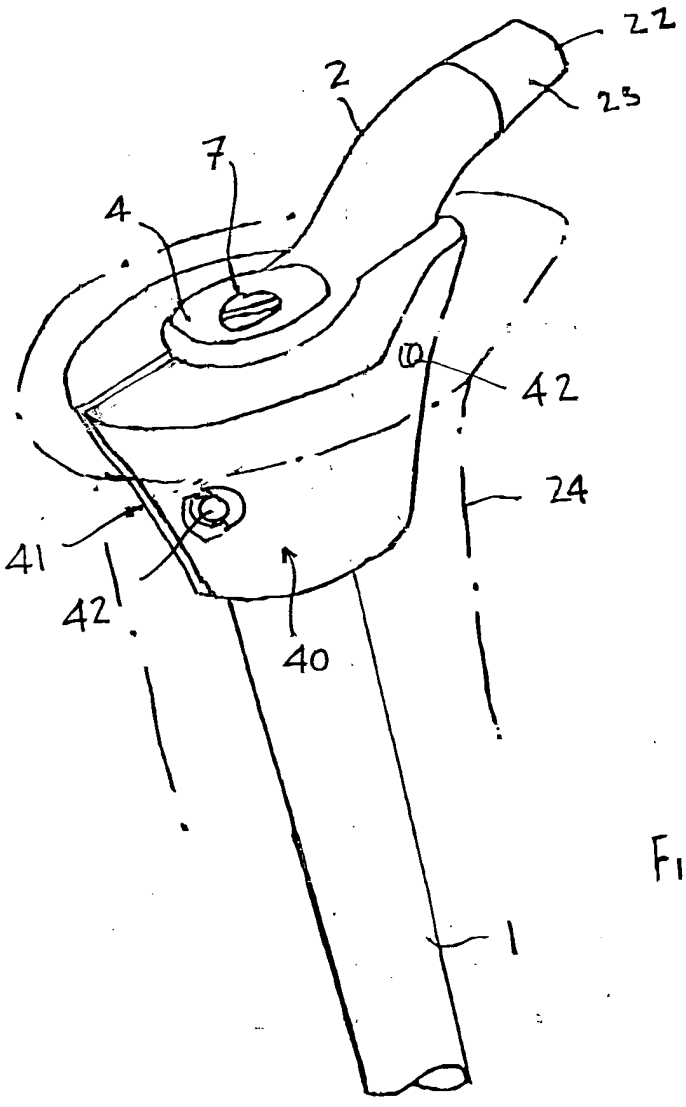

Fig 5

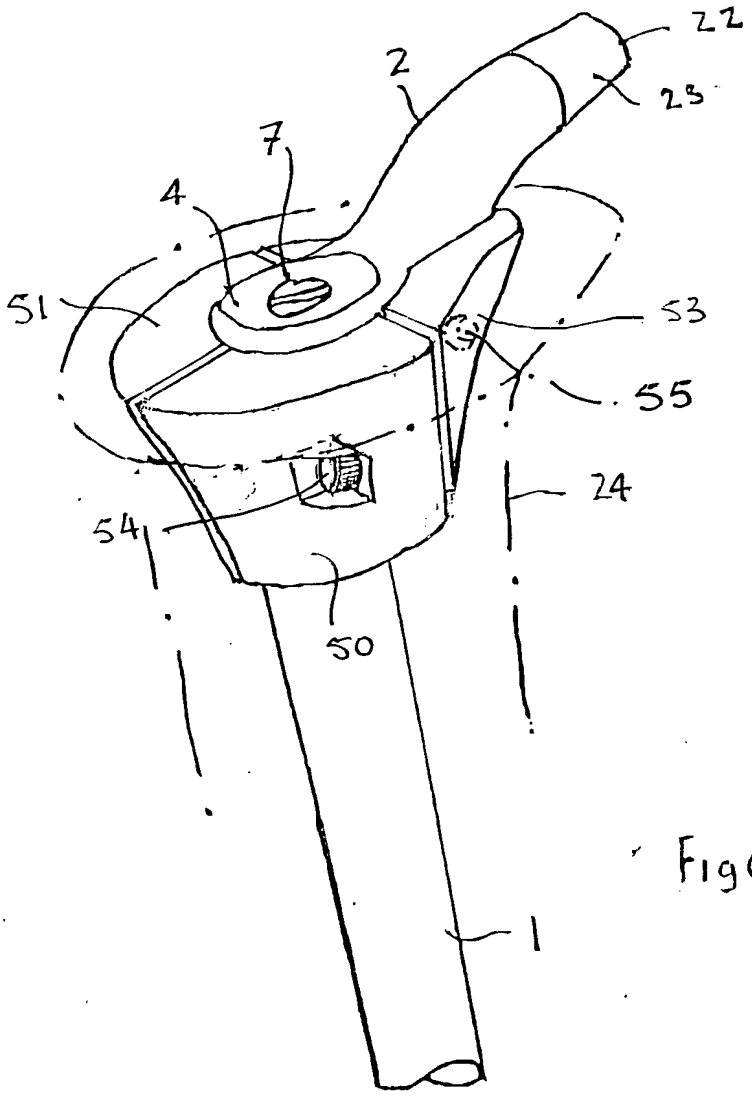

Fig6

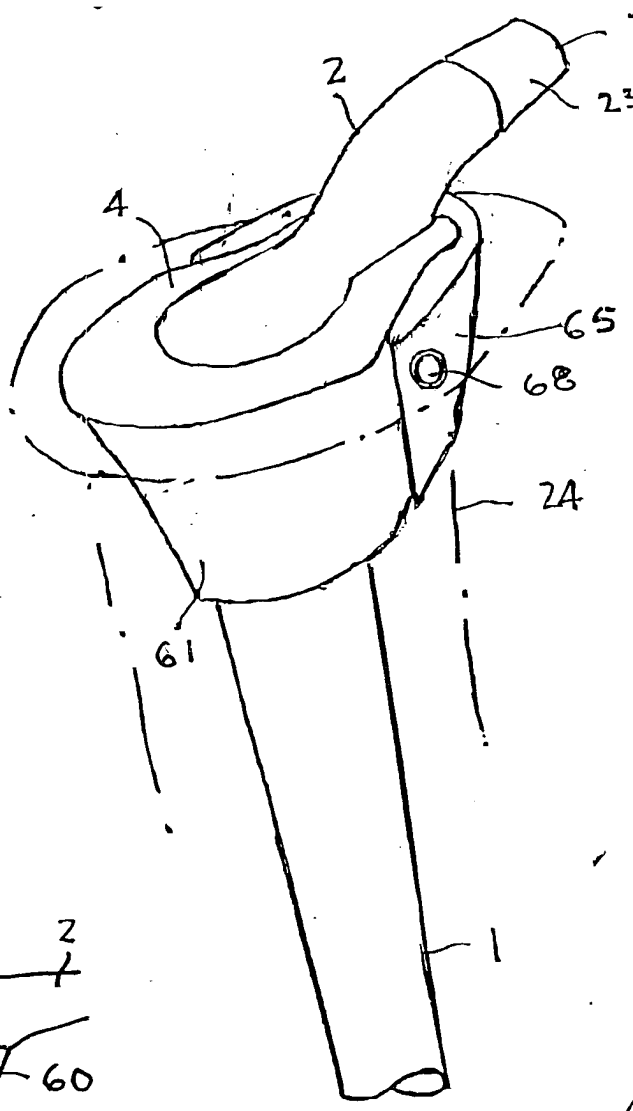

Fig 7

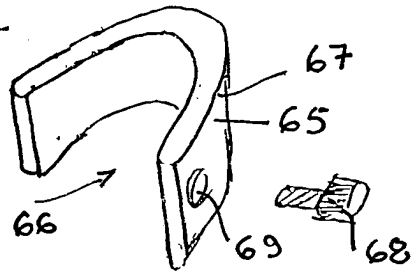

Fig 9

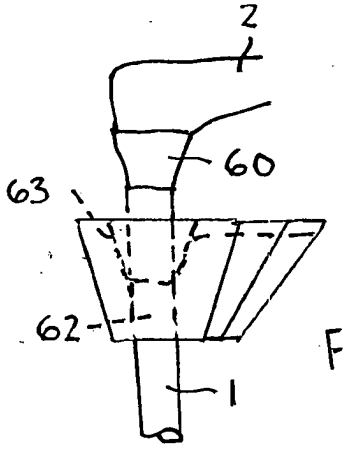

Fig 8

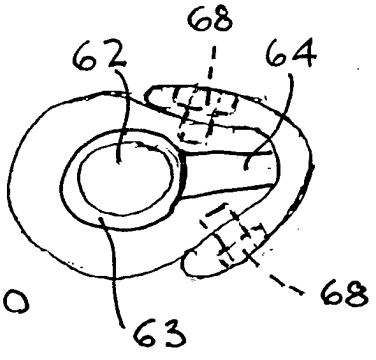

Fig 10

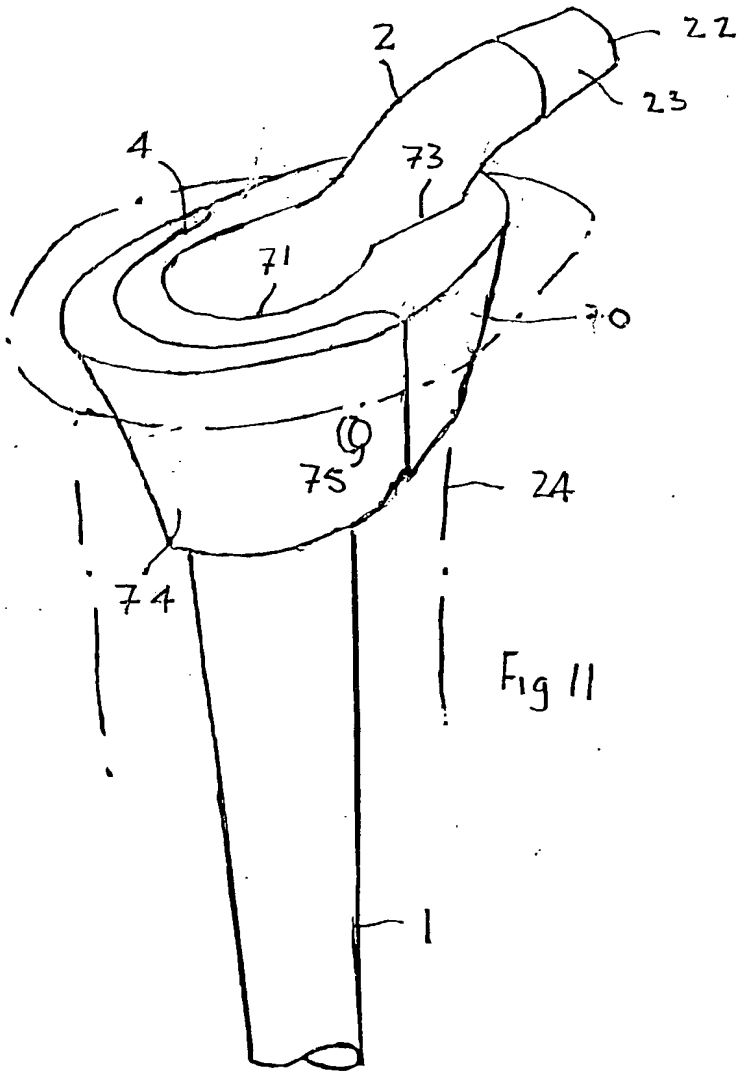

Fig 11

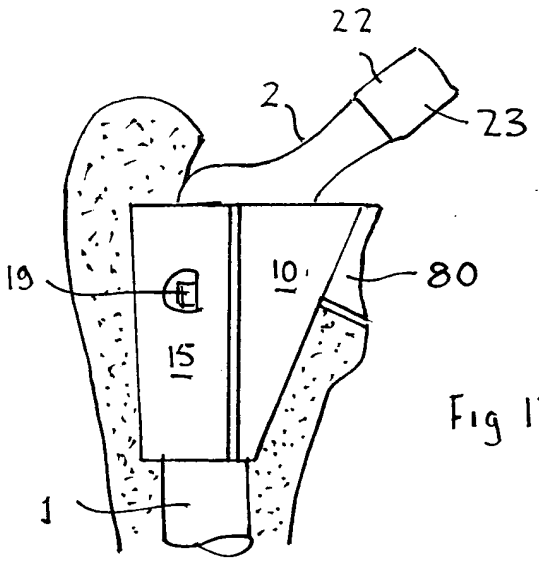

Fig 12

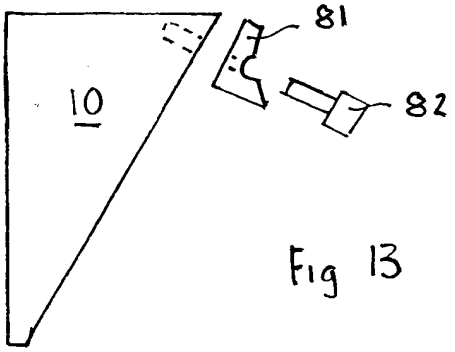

Fig 13